Patient information Leaflet for DIAXIGA

SCHEDULING STATUS

S4

DIAXIGA 5 film-coated tablets

DIAXIGA 10 film-coated tablets

Dapagliflozin

Contains sugar.

DIAXIGA 5: Each tablet contains 48,5 mg lactose anhydrous.

DIAXIGA 10: Each tablet contains 97,0 mg lactose anhydrous.

Read all of this leaflet carefully before you start taking DIAXIGA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DIAXIGA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DIAXIGA is and what it is used for
2. What you need to know before you take DIAXIGA
3. How to take DIAXIGA
4. Possible side effects
5. How to store DIAXIGA
6. Contents of the pack and other information.

1. What DIAXIGA is and what it is used for

DIAXIGA contains the active ingredient dapagliflozin, which belongs to a group of medicines called oral antidiabetics. DIAXIGA is used if your type 2 diabetes cannot be controlled with different medicines for diabetes, diet and exercise.

- Your doctor may ask you to take DIAXIGA alone or with another diabetes medicines.
- DIAXIGA increases the amount of sugar excreted by your kidneys.

DIAXIGA is not recommended for children and young people under the age of 18 years.

It is imponant to keep following the advice about diet and exercise given to you by your doclor, nurse, pharmacist or other health care provider.

2. What you need to know before you take DIAXIGA

Do not take DIAXIGA:

- If you are hypersensitive (allergic) to dapagliflozin or any of the other ingredients of DIAXIGA listed in section 6 of this leaflet.
- If you have kidney disease or are on dialysis.
- If you have type 1 diabetes mellitus.
- If you are pregnant or plan on becoming pregnant.
- If you are breastfeeding.

Warnings and precautions

DO NOT USE DIAXIGA IF YOU HAVE TYPE 1 DIABETES. DIAXIGA MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPT TYPE 2 DIABETES.

There have been reports of metabolic acidosis, including ketoacidosis, in patients taking DIAXIGA. Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalisation. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using DIAXIGA if you have

these conditions.

Diabetic ketoacidosis is a type of metabolic acidosis. Diabetic ketoacidosis is an increase of ketone bodies in your blood or urine, shown on blood or urine tests. Risk factors for diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not use DIAXIGA if you have these conditions.

Metabolic acidosis, including diabetic ketoacidosis, may occur in patients with type 2 diabetes mellitus with normal (blood glucose test result below 11 mmol/L) or high blood sugar levels who are treated with DIAXIGA. Contact a doctor or the nearest hospital straight away if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

Tell your doctor or pharmacist if:

- You are going to have surgery.
- You are eating less due to illness, surgery or you are dieting.
- You have or have previously had pancreas problems.
- You drink large amounts of alcohol.
- You develop any of the following symptoms, which may be an indication of diabetic ketoacidosis: nausea (feeling sick), vomiting (being sick), pain in the stomach area, excessive thirst, difficulty breathing, confusion and tiredness.

Tell your doctor or pharmacist immediately if you develop a combination of pain, tenderness, redness or swelling in your genital area or the area between the genitals and anus, with fever or a general unwell feeling. These symptoms could be a sign of a rare but serious infection called necrotising fasciitis of the perineum, or Fournier's gangrene.

Take special care with DIAXIGA:

- If you have kidney problems. Your doctor may prescribe you a different medicine or monitor your kidney function while you are being treated with DIAXIGA.
- If you have liver problems.
- If you are taking medicines to lower your blood pressure or a diuretic medicine (water pill) and have a history of low blood pressure.
- If your blood sugar levels are very high, as this may cause your body to dehydrate (lose too much water and salts).
- If you have or develop diarrhoea, nausea (feeling sick) or vomiting (being sick). This may also cause your body to dehydrate and your doctor may ask you to stop taking DIAXIGA until you recover.
- If you often get infections of the urinary tract.

As a diabetic patient, it is important to check your feet regulary and adhere to any other advice regarding foot care given to you by your doctor, pharmacist or other health care provider.

Due to the way DIAXIGA works, your urine will test positive for sugar while you are taking DIAXIGA.

Children and adolescents

DIAXIGA is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and DIAXIGA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor:

- If you are taking diuretic medicine (water pill) (used to lower blood pressure or remove excessive water from the body).
- If you are taking other medicines to lower your blood sugar levels, such as insulin or a group of medicines called sulphonylureas. Your doctor may want to lower the dose of your other medicines to prevent hypoglycaemia (too low levels of sugar in the blood).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DIAXIGA.

The use of DIAXIGA is not recommended during pregnancy or breastfeeding.

Driving and using machines

DIAXIGA can cause dizziness.Taking DIAXIGA with other medicines called sulphonylureas or with insulin can cause very low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision. These may affect your ability to drive and use machines. Do not drive or use machines until you know how DIAXIGA affects you.

DIAXIGA contains lactose

If you have been told by your doctor that you have an inolerance to some sugars, contact your doctor before taking DIAXIGA.

3. How to take DIAXIGA

Do not share medicines prescribed for you with any other person.

Always take DIAXIGA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one DIAXIGA 10 mg tablet each day.

Your doctor may prescribe you a different strength that is right for you.

Your doctor may prescribe you DIAXIGA together with other medicines to lower your blood sugar levels.

Your doctor will tell you how long your treatment with DIAXIGA will last. Do not stop treatment early.

If you have the impression that the effect of DIAXIGA is too strong or too weak, tell your doctor or pharmacist.

Swallow the tablet whole with water.

DIAXIGA can be taken with or without food.

If you are following a diabetic weight control diet, keep on with this while you are taking DIAXIGA.

If you take more DIAXIGA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you.

If you forget to take DIAXIGA

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DIAXIGA

Do not stop taking DIAXIGA unless your doctor tells you to. If you have any further questions on the use of DIAXIGA, ask your doctor or pharmacist.

4. Possible side effects

DIAXIGA can have side effects.

Not all side effects reported for DIAXIGA are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while DIAXIGA, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking DIAXIGA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
  fainting,
- diabetic ketoacidosis (diabetic coma) (causing nausea (feeling sick), vomiting (being sick), pain in the stomach area, tiredness, thirst, passing of Iarge volumes of urine, shortness of breath and confusion),
- necrotising fasciitis of the perineum (causing pain, tenderness, redness and swelling of the genital area or area between the genitals and anus, along with fever and a general unwell feeling).

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- urinary tract infection (causing fever and/or chills, a burning sensation while urinating, an urge to frequently urinate,pain in your back or side and sometimes blood in your urine),
- low blood sugar levels, especially when taking DIAXIGA with insulin or a sulphonylurea (causing shaking, sweating, fast heartbeat, headache, changes in vision, a change in your mood and confusion),

Less frequent side effects:

- dehydration, volume depletion and hypovolaemia (loss of too much water from your body,

causing dry mouth and thirst, feeling tired or sleepy, passing little or no urine and a fast heartbeat).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- changes in test results when testing the amount of red blood cells in your blood,
- changes in test results when testing the amount of cholesterol (fat) in your blood,
- changes in test results when testing your kidney function,
- genital infections, including vaginal and penile thrush (causing irritation and itching in the area, discomfort while urinating and an increased amount of discharge) and inflammation of the penis glans (head) (causing tightness and redness of the skin, itching, irritation, an unpleasant smell and painful urination),
- high glucose (sugar) levels in the urine when tested,
- painful or difficult urination, urinating more or more frequently than usual,
- dizziness,
- rash,
- back pain,

Less frequent side effects:

- changes in test results when testing your blood creatinine or urea levels,
- decreased blood pressure,
- urinating more frequently during the night,
- genital itching,
- thirst or a dry mouth,
- constipation,
- excessive sweating,
- decreased weight,

Side effects with an unknown frequency:

- headache when DIAXIGA is taken with metformin,
- diarrhoea and nasopharyngitis (causing a runny or stuffy nose, coughing, sore throat, watery eyes, headache and tiredness) when DIAXIGA is taken with pioglitazone,
- bone fractures if you suffer from kidney problems.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIAXIGA.

5. How to store DIAXIGA

- Store at or below 25°C.
- Keep tablets in original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIAXIGA contains

The active substance is dapagliflozin.

DIAXIGA 5: Each tablet contains 5 mg dapagliflozin.

DIAXIGA 10: Each tablet contains 10 mg dapagliflozin.

The other ingredients are crospovidone (E1202), hypromellose (E464), lactose anhydrous, microcrystalline cellulose (E460), Opadry white (containing hypromellose(E464), macrogol (E1521), titanium dioxide (E171) and talc (E553b), poloxamer 407, silicon dioxide (E551) and sodium stearyl fumarate.

What DIAXIGA looks like and contents of the pack

DIAXIGA 5: White to off-white coloured, round shaped, film coated tablets, debossed with “1380” on one side and plain on the other side.

DIAXIGA 10: White to off-white coloured, oval shaped film coated tablet, debossed with “1381” on one side and plain on the other side.

DIAXIGA is packed in a white, round HDPE bottle with a white child resistant polypropylene closure and a 2 g desiccant bag.

Pack size: 30 tablets.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

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0157

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